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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/599,500

09/29/2006

Jong Soo Woo

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EXAMINER

HUANG, GIGI GEORGIANA

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

03/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,500	Applicant(s) WOO ET AL.	
	Examiner GIGI HUANG	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/7/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. The amendment filed December 7, 2007 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
 - (A) Claim 1 has been amended.
 - (B) Claim 5 have been cancelled.
 - (C) The specification has been amended.
2. Claims 1-4 are pending in the case.
3. Claims 1-4 are present for examination.
4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.

Information Disclosure Statement

5. The reference Lalor et al. has been considered.

Response to Arguments

6. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanghvi et al. (U.S. Pat. Publication No. 2007/0109891) in view of Shell et al. (U.S. Pat. No. 6340475).

Claim 5 is cancelled and moot.

7. Applicant's arguments see pages 1-8 filed 12/7/2007 have been fully considered and are not persuasive. Applicant's arguments that Sanghvi recites the negative recitation of not including polyethylene oxide are not persuasive. Sanghvi does not specifically teach the incorporation of polyethylene oxide, but there is no negative

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recitation for its exclusion. Applicant's arguments that Shell does not teach the combination of polyethylene oxide and a gum such as xanthan gum is not persuasive. Shell specifically teaches that the water-swelling polymer can be used individually or in combination and that certain combinations will provide an increase controlled release of the drug than when the components are used individually.

Shell even specifically teaches the combination of poly(ethylene oxide) with xanthan gum as a combination that will provide an increase controlled release of the drug than when the components are used individually (see Col. 9, lines 41-60). Applicant's arguments with respect to the ratios are not persuasive as the ratios are taught and met (see previous office action). Additionally, Shell also teaches the ratios for drug to polymers which would include the combinations taught. Applicant's arguments that the instant composition exhibits improved release due to the formulation and ratios are not persuasive as release rates are inherent properties to the composition and the limitation of the composition have been met. The comparative is not persuasive as it is not reflective to the rejection presented in the office action as it compares the components singularly and Shell teaches the combination and ratios.

The rejection of claims 1-4 under 35 U.S.C. 103(a) as being unpatentable over Sanghvi et al. (U.S. Pat. Publication No. 2007/0109891) in view of Shell et al. (U.S. Pat. No. 6340475) is maintained.

Conclusion

8. Claims 1-4 are rejected.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612